UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,380	07/25/2002	Aharon Shulov	24871	9209

20529 7590 08/08/2006

NATH & ASSOCIATES
112 South West Street
Alexandria, VA 22314

EXAMINER	
WINSTON, RANDALL O	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,380	SHULOV ET AL.	
	Examiner	Art Unit	
	Randall Winston	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 8-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 8-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Upon further review, the rejection made under the 35 U.S.C. 103(a) rejection set forth in examiner's final rejection on 11/15/2005 and examiner's advisory action on 04/21/2006 has been overcome by Applicant's amendment.

Since applicant has overcome the 35 U.S.C. 103(a) rejection, there will be a new grounds of rejections. Thus, this office action is made non-final.

Examiner has acknowledged by applicant that claims 6-7 have been cancelled.

Claims 1-5 and 8-18 will be examined on the merits.

Claim Objections

Claims 3 and 4 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 5 and 8-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first

paragraph. Applicant is directed to the Guidelines for the Examination of Paten Applications under the 35 U.S.C. 112. ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, NO. 4, pages 1099-111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

A review of the language of the claim indicates that these claims are drawn to a genus of the snake family selected from the group of snake families consisting of Atractaspidae, Elapidae, Crotalidae, Hydrophidae and Viperidae.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly and Co., 119 F3d 1559, 1569, 43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states "An adequate written description of a DNA"... required a precise definition, such as by

structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention".

There is a single species of the claimed genus disclosed that is within the scope of the claimed genus of the snake family selected from the group of snake families consisting of Atractaspidae, Elapidae, Crotalidae, Hydrophidae and Viperidae. The specification on page 15 lines 5-17 discloses the single species such as "Vipera palestinae" and "Vipera russelli" that is within the claimed genus of the snake family of Viperidae. Furthermore, on page 16 lines 5-28 of the specification discloses the single species such as "Crotalus adamanteus" that is within the claimed genus of the snake family of "Crotalidae and as well as the specification discloses the single species such as "Naja melanoleuca" that is within the claimed genus of the snake family Elapidae.

The disclosure of a single disclosed species (i.e. "Vipera palestinae" "Vipera russelli" "Crotalus adamanteus" "Naja melanoleuca") may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species that are not further described. There is substantial variability among the species. (please note: examiner acknowledges that there is substantial variability among snake venom because Sanders US 4162303, column 7 lines 57-58, teaches that snake venom various widely from different snakes)

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of the snake family selected from the group of snake families consisting of Atractaspidae, Elapidae, Crotalidae, Hydrophidae and Viperidae.

The specification does not "clearly allow persons of ordinary skill in the art to recognize that (he or she) invented is claimed" (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1-2, 5 and 8-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for a pharmaceutical composition, its use as an analgesic (i.e. relief of pain) and its preparation method comprising a substantially non-toxic fraction isolated from snake venom having the characteristics of a fraction purified from said venom by Mono Q ion-exchange chromatography and eluting the fraction with an aqeous buffer, wherein said fraction has an analgesic effect after a lag period, and wherein said snake venom species are "Vipera palestinae" "Vipera russelli" "Crotalus adamanteus" "Naja melanoleuca", the specification does not enable any person in the art for preparing a pharmaceutical composition, its use as an analgesic (i.e. relief of pain) and its preparation method comprising a substantially non-toxic fraction isolated from snake venom having the characteristics of a fraction purified from said venom by Mono Q ion-exchange chromatography and eluting the fraction with an aqeous buffer, wherein said fraction has an analgesic effect after a lag period, and wherein said snake venom families are Atractaspidae, Elapidae, Crotalidae, Hydrophidae and Viperidae.

The factors to be considered in determining whether undue experimentation is required are summarized in In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; © the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicant claims a pharmaceutical composition, its use as an analgesic (i.e. relief of pain) and its preparation method comprising a substantially non-toxic fraction isolated from snake venom having the characteristics of a fraction purified from said venom by Mono Q ion-exchange chromatography and eluting the fraction with an aqeous buffer, wherein said fraction has an analgesic effect after a lag period, and wherein said snake venom families are Atractaspidae, Elapidae, Crotalidae, Hydrophidae and Viperidae. Applicant has reasonably demonstrated on page 15, lines 5-17 and on page 16, lines 5-28 of the specification a pharmaceutical composition, its use as an analgesic (i.e. relief of pain) and its preparation method comprising a substantially non-toxic fraction isolated from snake venom having the characteristics of a fraction purified from said venom by Mono Q ion-exchange chromatography and eluting the fraction with an aqeous buffer, wherein said fraction has an analgesic effect after a lag period, and wherein said snake venom species are "Vipera palestinae" "Vipera russelli" "Crotalus adamanteus" "Naja melanoleuca". Applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a pharmaceutical composition, its use as

an analgesic (i.e. relief of pain) and its preparation method comprising a substantially non-toxic fraction isolated from snake venom having the characteristics of a fraction purified from said venom by Mono Q ion-exchange chromatography and eluting the fraction with an aqeous buffer, wherein said fraction has an analgesic effect after a lag period, and wherein said snake venom families are Atractaspidae, Elapidae, Crotalidae, Hydrophidae and Viperidae.

Moreover, it should be noted that the state of the prior art at the time the invention was filed did not recognize a pharmaceutical composition, its use as an analgesic (i.e. relief of pain) and its preparation method comprising a substantially non-toxic fraction isolated from snake venom having the characteristics of a fraction purified from said venom by Mono Q ion-exchange chromatography and eluting the fraction with an aqeous buffer, wherein said fraction has an analgesic effect after a lag period, and wherein said snake venom families are Atractaspidae, Elapidae, Crotalidae, Hydrophidae and Viperidae. For example, Sanders US 4162303, column 7 lines 57-58, teaches that snake venom various widely from different snakes. Thus, the art is silent regarding the efficacy of applicant's pharmaceutical composition, its use as an analgesic (i.e. relief of pain) and its preparation method comprising a substantially non-toxic fraction isolated from snake venom having the characteristics of a fraction purified from said venom by Mono Q ion-exchange chromatography and eluting the fraction with an aqeous buffer, wherein said fraction has an analgesic effect after a lag period, and wherein said snake venom families are Atractaspidae, Elapidae, Crotalidae,

Hydrophidae and Viperidae. Therefore, applicant's claimed method is unpredictable in the art.

Furthermore, applicant has reasonably demonstrated on page 15, lines 5-17 and on page 16, lines 5-28 of the specification a pharmaceutical composition, its use as an analgesic (i.e. relief of pain) and its preparation method comprising a substantially non-toxic fraction isolated from snake venom having the characteristics of a fraction purified from said venom by Mono Q ion-exchange chromatography and eluting the fraction with an aqeous buffer, wherein said fraction has an analgesic effect after a lag period, and wherein said snake venom species are "Vipera palestinae" "Vipera russelli" "Crotalus adamanteus" "Naja melanoleuca". Applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a pharmaceutical composition, its use as an analgesic (i.e. relief of pain) and its preparation method comprising a substantially non-toxic fraction isolated from snake venom having the characteristics of a fraction purified from said venom by Mono Q ion-exchange chromatography and eluting the fraction with an aqeous buffer, wherein said fraction has an analgesic effect after a lag period, and wherein said snake venom families are Atractaspidae, Elapidae, Crotalidae, Hydrophidae and Viperidae.

Therefore, it would require undue experimentation by one of skill in the art to practice the invention commensurate in scope with the claims.

Please Note claims 1-5 and 8-18 are free of the art because there is no motivation in the prior art to prepare a pharmaceutical composition, its use as an

analgesic (i.e. relief of pain) and its preparation method comprising a substantially non-toxic fraction isolated from snake venom having the characteristics of a fraction purified from said venom by Mono Q ion-exchange chromatography and eluting the fraction with an aqeous buffer, wherein said fraction has an analgesic effect after a lag period, and wherein said snake venom species are "Vipera palestinae" "Vipera russelli" "Crotalus adamanteus" "Naja melanoleuca".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan Hoffman
8-3-06
SUSAN COE Hoffman
PRIMARY EXAMINER